FRESENIUS MEDICAL CARE

NOV - 9 2012

510k Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

A. Submitter's Information

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Date of Preparation:	31 May 2012

B. Device Name

Trade Name:	CLiC Monitor (Crit-Line Clip Monitor)
Classification Name	Non-invasive Hematocrit, Oxygen Saturation, Percent change in blood volume Monitor
Classification Number	Class II per § 876.5820
Product Code/Classification Panel:	78 MQS/Gastroenterology/Urology Panel

C. Legally Marketed Predicate Device (unmodified device)

Crit-Line III Monitor (K972470).

D. Device Description

The intended use of the Crit-Line III (CLM III) Monitor is as a continuous real-time monitor for non-invasive hematocrit, oxygen saturation, and percent change in blood volume measurement. The CLM III is used primarily as a monitor for dialysis treatments.

The CLM III uses the principle of light absorption and scattering through the blood under test to measure oxygen saturation (O_2 SAT) and hematocrit (HCT). The HCT values are then used to calculate the related Blood Volume (BV) percentage change relative to the starting BV based on the beginning HCT.

The CLM III consists of a microprocessor-controlled main circuit board located within the display housing. The display housing contains the sensor clip driver measurement-calculation circuitry and display screen circuitry. The sensor clip with optical system (LED array and a photodetector array) is tethered to the main housing and circuit board by a multi-conductor cable. The cable connects to a single-use, sterile cuvette (K935958) installed in-line with the arterial line of the dialysis tubing set.

Calculations performed on the main circuit board within the display housing yield the hematocrit, oxygen saturation and the related value of blood volume measurement results and are displayed on the LCD display screen.

Modifications to the previously cleared Crit-Line III Monitor include:

3. Miniaturization/Re-packaging

The CLiC Monitor incorporates all hardware/electronic components – miniaturized and contained within the sensor clip housing, for measuring indicated parameters (HCT O_2 SAT). The primary modification of the device involves integrating a miniaturized microprocessor with the required electronic circuitry and software to drive the existing optical system (LED and photo-detector array) within the plastic sensor clip housing. The CLiC utilizes the same, previously cleared Crit-Line technology (K972470), sensor clip and optical system. The operating principles and fundamental measurement methods of the CLiC are the same as the predicate device.

4. Distributed Process Technology

A standard USB cable replaces the tethering multi-conductor cable used in the CLM III Monitor. USB-compatible hardware and software are incorporated in the CLiC housing. The CLiC can be hosted on a medical grade computer system (Windows OS) that can interface with, power a USB peripheral and operate supporting drivers. CLiC interlocks with a single-use, sterile cuvette (K935958) which is located in-line with the arterial line of the dialysis tubing set for indicated measurements. The lightwave measurements are performed autonomously by the CLiC. Blood parameters are then calculated and transmitted to the host computer display microprocessor in text format by means of the USB interface. The accompanying display software installed on the host computer system facilitates the display of measured parameters: hematocrit, oxygen saturation and blood volume changes on the display screen.

E. Indications for Use

The Crit-Line Clip Monitor (CLiC) is used to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The CLiC measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the dialysis technician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e. increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.

F. Technological Characteristics

The CLiC Monitor is a compact measurement device which can be used with any medical grade computer system (Windows OS) that can interface with and power a USB peripheral. With the supporting display software, the Windows-based computer system provides the user interface.

The CLiC is a modification to the Crit-line III with equivalent indications for use, to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. Both devices non-invasively measure blood parameters using multiple wavelengths of light

which are scattered and absorbed, respectively, by different constituents in the blood. The CLiC Monitor has the same operating principle and fundamental scientific technology as the predicate device. It is also comparable to the predicate device in terms of key safety, effectiveness, and quality assurance features.

The CLiC Monitor is designed and developed using product specifications, construction and manufacturing methods functionally equivalent to the predicate device. The plastic sensor clip housing and optical system (LED illuminators and photodetectors) are same the as the predicate device (K972470).

The modifications described in this submission have not altered nor do they have the potential to alter the fundamental scientific technology of the device.

FMCNA has concluded that the CLiC Monitor is of comparable type and substantially equivalent to the currently marketed Crit-line III, complies with the same or equivalent standards and has the same intended use. In addition, the CLiC Monitor is certified to comply with safety requirements of UL 60601-1/IEC 60601-1, and EMC standard 60601-1-2.

The following technical specifications of the modified device remain the same as the unmodified device:

- LED illuminators and Photodetector arrays
- Safety system
- System performance
- Environmental Requirements
- Transportation and Storage condition
- User Interface (except USB port and display software on host computer system)
- Hardware (except miniaturization)
- Environmental Design
- Alarms
- Accuracy and Controls
- Protection against excessive temperature or other hazards
- Manufacturing Location and manufacturing processes (testing, shipping, installation and service).

Safety and effectiveness of the CLiC Monitor is confirmed by:

- System verification and validation testing – to verify performance to specifications, applicable referenced FDA regulations, and user requirements.

- Adherence to FDA-recognized industry and international standards (IEC 60601-1 and IEC 60601-1-2) - Electrical Safety and Electromagnetic Compatibility testing was conducted to ensure the safety and effectiveness of the device after the proposed modifications.

A risk analysis, per ISO 14971, has been completed and potential hazards associated with the modifications are identified and mitigated. Mitigations are verified wherever applicable. All potential risks were deemed acceptable after mitigation.

G. Performance Data

The performance of the modified device was evaluated according to existing procedures, protocols, declared performance standards and guidelines of the quality system regulation (21 CFR 820). Design verification and validation tests were conducted to ensure that the modifications described in this submission did not affect the essential performance of the device and the device functions as intended.

The CLiC Monitor accuracy is equivalent to the predicate device specifications for both hematocrit and oxygen saturation measurements. Because blood volume calculations are based on hematocrit and the CLiC Monitor matches the predicate specifications, the percentage blood volume comparisons are also equivalent.

H. Conclusion

The CLiC Monitor does not pose any new potential safety risks and performs the same measurement functions as the predicate device.

Test results demonstrated that the modified CLiC Monitor functions as intended and met pre-determined acceptance criteria. Results of performance testing (in vitro bench testing), safety testing and usability testing indicate that the modified CLiC device is substantially equivalent to the named predicate device and remains safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 9, 2012

Fresenius Medical Care - North America
% Ms. Denise Oppermann
Senior Director, Regulatory Affairs Devices
920 Winter Street
WALTHAM MA 02451

Re: K121599
Trade/Device Name: Crit-Line Clip (CLIC) Monitor
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC
Dated: October 10, 2012
Received: October 11, 2012

Dear Ms. Oppermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K121599

Device Name:

Crit-Line Clip (CLiC) Monitor

Indications for Use:

The Crit-Line Clip Monitor (CLiC) is used to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. CLiC measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the dialysis technician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e. increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.

☒Prescription Use
(Per 21 CFR 801 Subpart D)

AND/OR

☐Over-the-Counter Use
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121599